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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/899,595	07/05/2001	Stefanie Sprunck	514413-3885	7610

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EXAMINER

KALLIS, RUSSELL

ART UNIT	PAPER NUMBER
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1638

14

DATE MAILED: 10/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/899,595

Applicant(s)

SPRUNCK ET AL.

Examiner

Russell Kallis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 14-16 is/are pending in the application.
- 4a) Of the above claim(s) 14 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12, 15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

Claims 1-12 and 14-16 are pending in the Application. Claim 13 has been cancelled.

Claims 1-12 and 15 are Examined.

Rejection of Claims 1-2 under 35 U.S.C. 101 is withdrawn in view of Applicant's arguments.

Rejection of Claims 1 and 2 under 35 U.S.C. 102(b) *Li et al.* is withdrawn in view of Applicant's argument's.

### ***Election/Restrictions***

Applicant asserts that SEQ ID NOs: 1-10 cannot be considered patentably distinct because they are members of a single structurally and functionally related genus (response page 4, lines 23-25) and all of SEQ ID NO: 1-10 have the structure and function of a caryopsis specific promoter (response 5, lines 5-8). The definition of a genus requires that all elements of the genus share common structural features to each other. In the relationship of SEQ ID NO: 1-10, SEQ ID NO: 2-10 share identity to discrete portions of SEQ ID NO: 1 but not to each other and not to the entirety of SEQ ID NO: 1. And since there is nothing in the specification demonstrating that any of the promoter sequences SEQ ID NO: 2-10 separately operate in a caryopsis specific fashion the SEQ ID NO: 1-10 are independent and distinct. Furthermore, since 1996 resources at the Patent office have changed and the examination and search of more than one sequence would pose an undue burden.

The requirement is still deemed proper and remains FINAL.

***Claim Rejections - 35 USC § 112***

Claims 1-12 and 15 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant asserts that a representative number of species are described by stringent hybridization conditions and 75-99% sequence identity to SEQ ID NO: 1 (response pages 5-6). It is noted that Claim 1 recites various characteristics in the alternative, given the recitation of “and/or”, so that the nucleic acid molecule is not required to possess 75-99% identity to the sequences of part a. Applicant does not define the hybridization conditions. Stringency is a relative term comprising low, moderate or highly stringent hybridization conditions. Further, hybridization conditions are to be recited in the claims. Furthermore, recitation of a percent sequence identity limitation to a particular sequence having a known function does not meet the written description guidelines since the guidelines require a description of said percent identity sequence that correlates to the claimed function to lay claim to a genus. Furthermore, the claims may be interpreted to read only on part c) of Claim 1, namely a “functional portion” of part a). “Functional portions” are defined on page 18 of the specification, lines 16-19, as any variant with reduced promoter activity. This reads on single nucleotide fragments with reduced (i.e. no) promoter activity.

Applicant is invited to review their rebuttal of the anticipation rejection over Li *et al.* on page 8 of their response. Li teaches a promoter which constitutes a “functional portion” of SEQ ID NO: 1 and which would hybridize thereof under conditions of low to moderate stringency,

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given it has 49.5% identity (according to Applicant's analysis), but which is not caryopsis specific. Further, Applicant is asked to reconsider the USPTO alignment where it is clearly demonstrated that there is 99.7% sequence identity between a fragment of SEQ ID NO: 1 and a portion of the Li sequence. In view of this fact even hybridization conditions of high stringency would not eliminate promoter elements that are not caryopsis specific. This clearly indicates that the claims are not describing caryopsis specific elements.

Claims 1-12 and 15 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a caryopsis-specific promoter of SEQ ID NO: 1 and caryopsis-specific functional portions comprising positions 2241 to 4683 and 4071 to 4683 of SEQ ID NO: 1 from wheat, does not reasonably provide enablement for any caryopsis-specific promoter comprising one or more of the sequence elements consisting of SEQ ID NOs: 2-10; or comprising any functional portion of the SEQ ID NO: 1; or a sequence having 60-99% sequence identity to SEQ ID NO: 1, or any sequence hybridizing thereto under unspecified conditions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Applicant asserts that the structure of the claimed molecules of 75-99 % sequence identity are unambiguously recited, that guidance is provided for determining activity, and processes for determining structural characteristics are standard in the art (response page 6, lines 15-23). It is important to note that although one skill in the art can make substitutions and other modifications to a sequence Applicant has not provided guidance for substitution or deletions of sequences of SEQ ID NO: so that non-functional embodiments can be predictably avoided.

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Applicant is reminded that the claims may be interpreted to read on any single part of Claim 1, to the exclusion of part c), as stated above.

Applicant asserts that the Benfey *et al.* reference is not relevant to the instant application because methods available to the expert have improved and predicted promoter activity is easily verified, and points to pages 30-35 of the specification that teach several known seed specific expression elements of promoters (response page 7). Applicant has claimed changes to SEQ ID NO: 1 that are broad and unspecified that would recapitulate the unpredictability described in the Benfey article in spite of the improvements of promoter verification in the art. Applicant has not taught which specific combination of elements are required for caryopsis specific activity as well as which seed specific elements or required combinations of elements when altered, substituted, deleted or recombined would retain the caryopsis specific expression of the claimed invention given the breadth and indefiniteness of the claims. Furthermore given the lack of written description for functional portions of promoter fragments and elements that are caryopsis specific as discussed supra, methods of using said functional portions are not enable as well.

Given the lack of guidance for isolating and identifying caryopsis specific promoters or functional portions comprising any number of non-exemplified sequence elements, the limited working examples in the specification that would exemplify combinations of caryopsis specific elements from a variety of non-exemplified sources, the breadth of the claims, and the unpredictability in the art, undue trial and error experimentation would have been required by one skilled in the art to evaluate a multitude of non-exemplified caryopsis-specific promoters.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claim 1, line 9, “stringency” is a relative term and therefore indefinite because it is not clear whether conditions of low, moderate or high unspecified stringency are intended.

***Claim Rejections - 35 USC § 102***

Claims 1-12 and 15 remain rejected under 35 U.S.C. 102(b) as being anticipated by Robert L. *et al.*, Plant Cell, December 1989, Vol. 1, pp. 569-578.

The claims broadly recite “a sequence which hybridizes with at least one of the nucleotide sequences stated under a)” under conditions of unspecified time, temperature, and salt concentration; and a “functional portion of the nucleic acid stated under a)” of unspecified length and activity.

Applicant asserts that the percent identity of the Robert *et al.* reference falls outside the percent identity limitations of the claims (response pages 8-9) and that the reference does not anticipate or render obvious claims 1-12 and 15 because it does not teach isolation of a caryopsis specific promoter. Applicant has not claimed a method of isolating a caryopsis specific promoter, but rather Applicant has claimed an isolated caryopsis specific promoter and methods of generating transformed plants therewith and a method for caryopsis specific gene expression in plants of unspecified phylogeny. The claims may also be interpreted to exclude the recited sequence identity as discussed above. Since Applicant recites unspecified hybridization

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conditions, as discussed supra, and since Robert teaches endosperm specific expression of CAT in tobacco seeds, transformed with a wheat (monocot) high molecular weight glutenin endosperm/caryopsis specific promoter, 8 days after anthesis (Abstract, lines 1-13 and page 573 column 2, lines 19-26), an expression cassette and vector, host cell, and transformed plants (page 570, column 1), the reference teaches all the limitations of Claims 1-12, and 15.

No Claim is Allowed.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.



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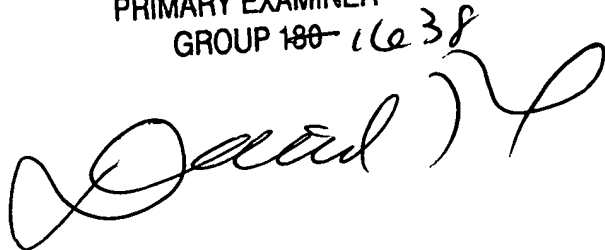
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (703) 305-5417. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0198.

Russell Kallis Ph.D.  
September 25, 2003

DAVID T. FOX  
PRIMARY EXAMINER  
GROUP 180-1638

A handwritten signature in black ink, appearing to read "David T. Fox", is written over the printed name and title.